REMARKS

After entry of this amendment, claims 1-54 and 56-78 will be perding for the Examiner's review and consideration. The Office Action dated May 18, 2004 has been carefully considered. Claims 1, 21, 35, 40, 41, and 77 have been amended. No new matter has been added. Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated May 18, 2004, the Examiner:

- rejected claims 77-78 under 35 U.S.C. § 102(a) as being ar icipated by United
 States Patent No. 5,899,939 to Boyce ("Boyce");
- rejected claims 1-54, 58-59, 61, 67-68 and 71-73 under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of United States Parent No. 4,950,296 to McIntyre ("McIntyre");
- rejected claims 56-57, 60, 62-66, 69-70, and 74-76 under 35 U.S.C. § 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Boyce.

Independent Claim 1

Independent claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of McIntyre. Independent claim 1 has been amended to recite, inter alia, an implant comprising a body having a substantially tubular inner member and at least one substantially tubular outer member, each member being formed with an exterior surface and an opening defining an interior surface, wherein the exterior surface of each inner member contacts the interior surface of no more than one other outer member. There is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a body having a substantially tubular inner member and at least one substantially tubular outer member, each member being formed with an exterior surface and an opening defining an interior surface, wherein the exterior surface of each inner member contacts the interior surface of the outer member.

Rather, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant

comprising a body having a substantially tubular inner member and at least one substantially tubular outer member. Moreover, Boyce does not disclose, teach, or suggest each member being formed with an exterior surface and an opening defining an interior surface wherein the exterior surface of each inner member contacts the interior surface of the outer member.

Furthermore, it is respectfully submitted that McIntyre does not rectify the failings of Boyce in this regard. Rather McIntyre discloses inserting a cancellous bone plug into an outer cortical shell. Thus, McIntyre does not disclose, teach, or suggest an implant comprising a body having a substantially tubular inner member and at least one substantially tubular outer member. Moreover, McIntyre does not disclose, teach, or suggest each member being formed with an exterior surface and an opening defining an interior surface wherein the exterior surface of each inner member contacts the interior surface of the cuter member. That is, McIntyre does not disclose, teach, or suggest each member being formed with an opening defining an interior surface.

Moreover, it is respectfully submitted that there is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a body having a substantially tubular inner member and at least one substantially tubular outer member, each member being formed from a bone from a different region in the body. Rather, Boyce discloses that one or more layers could be made from a material other than partially demineralized bone. Boyce however does not disclose, teach, or suggest an implant comprising a body having a substantially tubular inner member and at least one substantially tubular outer member, each member being formed from a bone from a different region in the body.

McIntyre, it is respectfully submitted, discloses inscrting a cancellous bone plug into an outer cortical cell wherein the cancellous bone plug is retrieved from the quee while the outer cortical cell is taken from the femur. It is respectfully submitted that McIntyre does not teach, disclose, or suggest an implant comprising a body having a substantially tubular inner member and at least one substantially tubular outer member, each member being formed from a bone from a different region in the body. That is, McIntyre does not teach, disclose, or suggest retrieving a substantially tubular inner member from a first region of the body and at least one substantially tubular outer member from a second region of the body.

Therefore, it is respectfully submitted that neither Boyce nor McIntyre, either singularly or in combination, disclose, teach, or suggest all of the elements of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Claims 2-20 all ultimately depend from independent claim 1, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2-20 is therefore respectfully requested.

Independent Claim 21

Independent claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of McIntyre. Independent claim 21 has been amended to recite an implant comprising a body formed from a core and a plurality of substantially tubular members wherein each member has an outer tubular surface and an opening defining an inner tubular surface, the outer surface of the first member has about the same contour as the inner surface of the second member so that the first member may be received within the second member, the core being sized and configured to be received within the opening formed in the first member. There is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a body formed from a core and a plurality of substantially tubular members wherein each member has an outer tubular surface and an opening defining an inner tubular surface so that the inner tubular member may be received within the opening formed in the outer tubular member, and the core may be received within the opening formed in the inner tubular member.

Rather, as previously stated, Boyce discloses taking a long bone and ·licing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, it is respectfully submitted, that Boyce does not disclose, teach, or suggest an implant formed from a core and a plurility of substantially tubular members. Moreover, Boyce does not disclose, teach or suggest an outer tubular member having an opening sized and configured to receive an inner tubular member which has an opening sized and configured to receive the core.

It is respectfully submitted that McIntyre does not rectify the shor comings of Boyce in this regard. Rather, McIntyre discloses inserting a cancellous bone plug into an outer cortical shell. Thus, McIntyre does not disclose, teach, or suggest an impant formed from a core and a plurality of substantially tubular members. Moreover, McIntyre does not disclose, teach or suggest an outer tubular member having an opening sized and configured to receive an inner tubular member which has an opening sized and configured to receive the core.

Therefore, it is respectfully submitted that neither Boyce nor McImyre, either singularly or in combination, disclose, teach, or suggest all of the elements of independent claim 21. Thus, it is respectfully submitted that independent claim 21 is a lowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 21 is respectfully requested.

Claims 22-39 all ultimately depend from independent claim 21, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawa, of these rejections and allowance of claims 22-39 is therefore respectfully requested.

Independent Claim 40

Independent claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of McIntyre. Independent claim 40 has been amended to recite an implant comprising a plurality of substantially circular members, each member having a hole defining an opening; the implant further including a core sized and configured to fit within the innermost circular member, wherein the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulua, and radius. There is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a plurality of substantially circular members, each member having a hole defining an opening; the implant further including a core sized and configured to fit within the innermost circular member.

Rather, as previously stated, Boyce discloses taking a long bone and a icing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclost, teach, or suggest an implant comprising a plurality of substantially circular members, each member

having a hole defining an opening; the implant further including a core sized and configured to fit within the innermost circular member.

It is respectfully submitted that McIntyre does not rectify the shortcomings of Boyce in this regard. Rather, McIntyre discloses inserting a cancellous bone plug into a cavity of an outer cortical shell. Thus, McIntyre does not teach, disclose, or suggest an implant comprising a plurality of substantially circular members, each member having a hole defining an opening; the implant further including a core sized and configured to fit within the innermost circular member.

Moreover, it is respectfully submitted that there is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a plurality of substantially circular members wherein the members are formed from at least two different bones selected from the group comprising a ferr ir, tibia, humerus, fibula, ulna, and radius. Rather, Boyce discloses that one or more layers could be made from a material other than partially demineralized bone. Boyce however does not disclose, teach, or suggest an implant comprising a plurality of substantially circular members wherein the members are formed from at least two different bones. Therein, Boyce cannot disclose, teach, or suggest the fact that the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

McIntyre, it is respectfully submitted, discloses inserting a cancellous bone plug into an outer cortical cell. The cancellous bone plug being retrieved from the knew while the outer cortical cell is taken from the femur. It is respectfully submitted that McInt, re does not teach, disclose, or suggest retrieving a plurality of substantially circular mer bers wherein the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

Therefore, it is respectfully submitted that neither Boyce nor McIntyre, either singularly or in combination, disclose, teach, or suggest all of the elements of independent claim 40. Thus, it is respectfully submitted that independent claim 40 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 40 is respectfully requested.

Independent Claim 41

Independent claim 41 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Boyce in view of McIntyre. Independent claim 41 recites an implant comprising a substantially circular inner member and at least one substantially circular outer member wherein the inner member is sized and configured to fit within an opening formed in the outer member. There is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a substantially circular inner member and at least one substantially circular outer member wherein the inner member is sized and configured to fit within an opening formed in the outer member.

Rather, as previously described, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The layers comprising alternating layers of fully mineralized cortical bone and partially demineralized cortical bone. Thus, it is respectfully submitted that Boyce does not disclose, teach or suggest an implant comprising a substantially circular inner member and at least one substantially circular outer member wherein the inner member is sized and configured to fit within an opening formed in the outer member.

It is respectfully submitted that McIntyre does not rectify the shorte mings of Boyce in this regard. Rather, McIntyre discloses inserting a cancellous bone plug into a cavity of an outer cortical shell. Thus, McIntyre does not teach, disclose, or suggest an inplant comprising a substantially circular inner member and at least one substantially circular outer member wherein the inner member is sized and configured to fit within an exening formed in the outer member.

Moreover, it is respectfully submitted that there is no disclosure, teaching, or suggestion in either Boyce or McIntyre, either singularly or in combination, of an implant comprising a substantially circular inner member and at least one substantially circular outer member wherein the implant is formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius. Rather, Hoyce discloses that one or more layers could be made from a material other than partially demineralized bone. Boyce however does not disclose, teach, or suggest an implant comprising a plurality of substantially circular members wherein the members are formed from at least two different

bones. Therein, Boyce cannot disclose, teach, or suggest the fact that the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

McIntyre, it is respectfully submitted, discloses inserting a cancellous bone plug into an outer cortical cell. The cancellous bone plug being retrieved from the linee while the outer cortical cell is taken from the femur. It is respectfully submitted that McIntyre does not teach, disclose, or suggest retrieving a plurality of substantially circular π embers wherein the members are formed from at least two different bones selected from the group comprising a femur, tibia, humerus, fibula, ulna, and radius.

Therefore, it is respectfully submitted that neither Boyce nor McIntyre, either singularly or in combination, disclose, teach, or suggest all of the elements of independent claim 41. Thus, it is respectfully submitted that independent claim 41 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 41 is respectfully requested.

Claims 42-54 all ultimately depend from independent claim 41, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 42-54 is therefore respectfully requested.

Independent Claim 56

Independent claim 56 was rejected under 35 U.S.C. § 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Ecyce. Independent claim 56 recites, inter alia, an implant comprising a body having two outer annular members and at least one inner annular member, wherein the outer annular members are coupled together to define a central opening for receiving the at least one inner member. There is absolutely no disclosure, teaching, or suggestion in Boyce of an implant comprising two outer annular members which are coupled together to define a central opening for receiving an inner member.

Rather, as previously stated, Boyce discloses taking a long bone and :licing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter

be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising two outer annular members which are coviled together to define a central opening for receiving an inner member.

Therefore, it is respectfully submitted that Boyce does not disclose, teach, or suggest all of the elements of independent claim 56. Thus, it is respectfully submitted that independent claim 56 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 56 is respectfully requested.

Claims 57-76 all ultimately depend from independent claim 56, and thus, it is respectfully submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 57-76 is therefore respectfully requested.

Independent Claim 77

Independent claim 77 was rejected under 35 U.S.C. § 102(a) as being anticipated by Boyce. Independent claim 77 has been amended to recite, *inter alia*, an implant comprising a body having at least two ring-shaped members formed from bone, wherein the innermost ring-shaped member has an outer diameter, the outermost ring-shaped member has a central opening defining an inner surface, the inner surface is sized and configured to receive the innermost ring-shaped member so that the innermost ring-shaped member is received within the outermost ring-shaped member.

There is no disclosure, teaching, or suggestion in Boyce of an implant comprising an innermost ring-shaped member and an outermost ring-shaped member wherein the innermost ring-shaped member is received within the outermost ring-shaped member.

Rather, as previously described, Boyce discloses taking a long bone and slicing it longitudinally to form bone layers, the layers then being superimposed one on top of the other in an edge-to-edge fashion in a manner "analogous to planking." The implant may thereafter be machined into any desirable size and shape. Thus, Boyce does not disclose, teach, or suggest an implant comprising an innermost ring-shaped member and an outermost ring-shaped member wherein the innermost ring-shaped member is received with a the outermost ring-shaped member.

Therefore, it is respectfully submitted that Boyce does not disclose, teach, or suggest all of the elements of independent claim 77. Thus, it is respectfully submitted that independent claim 77 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 77 is respectfully requested.

Claim 78 depends from independent claim 77, and thus, it is respectfully submitted that claim 78 is equally allowable. Withdrawal of this rejection and allowance of claim 78 is therefore respectfully requested.

In light of the above amendments and remarks, it is respectfully submitted that claims 1-53 and 55-78 are now in condition for allowance, and the Examiner is respectfully requested to reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at 212-326-7883, if a telephone call could help resolve any remaining issues.

Date: August 18, 2004

(Reg. No.)

For: Brian M. Rothery JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939